REMARKS/ARGUMENTS

Claims 44-107 are pending in this application. The elected Group III claims, namely nos 46, 52, 53, 59, 65, 70 and 90 are rejected, whereas non-elected claims 44, 45, 47-51, 54-58, 60-64, 66-69, 71-89 and 91-107 are withdrawn from consideration by the Examiner. Reconsideration of all of the claim rejections is respectfully requested based on the remarks below.

Claim Rejections Under 35 U.S.C. §103

On p. 2 of the Office Action, claims 46, 52, 53, 59, 65, 70 and 90 are rejected under §103 as allegedly lacking an Inventive Step over the combination of four references - Fatouros, M.S., et al., *Eur. J. Surg.* (1999), Krussel, J.S., et al., *Mol. Hum. Reprod.* (2001), EP 0613 683 (Amgen) and U.S. Patent No. 6,274,158 (Zaharia Czeizler). This ground of rejection is respectfully traversed.

To briefly summarize applicants' position, Fatouros discloses the influence of growth factors erythropoietin and GM-CSF on the healing of colonic anastomoses in rats. The reference, however, as noted by the Examiner, does not teach to utilize weekly doses of 1 to 90 International Units (IU) of EPO/kg of body weight. The Zaharia Czeizler patent refers to the treatment of bleeding in patients using erythropoietin. This reference discloses neither the treatment of wounds, nor the use of weekly doses of 1 to 90 IU EPO/kg of body weight. Proceeding further, EP 0613 683 of Amgen does disclose the administration of EPO to a patient by a pulmonary route, yet it contains no teaching directed to the use of such EPO for the treatment of wounds, nor does it contain any disclosure relating to the use of weekly doses of from 1 to 90 IU EPO kg/body weight. Finally, Krussel et al. discloses functions relating to VEGF. It does not, however, disclose the use of EPO to treat wounds, and in particular it does not disclose the use of weekly doses of 1 to 90 IU EPO kg/body weight, whether or not for the treatment of wounds.

Taking the above-noted lack of disclosure relating to applicants' claimed method into account, applicants respectfully submit that in their view, the combined disclosure of the four cited references would not suggest the presently claimed method to one having ordinary skill in this field of art. That is, for the reasons developed more fully in the discussion which follows, the presently claimed method recited in claims 46, 52, 53, 59, 65, 70 and 90 is believed to demonstrate an Inventive Step over the teachings of the cited references, whether taken individually or in combination.

To begin with, none of the cited references teach the claimed does range of 1 to 90 IU EPO/kg body weight per week. The Examiner, however, seems to view this feature of the claimed method as representing only a 'routine optimization' of the dosage necessary to carry out the subject method, and, thus, well within the ordinary skill of one working in this art. Applicants respectfully disagree, however. The dosage recited in applicants' claims is significantly lower than that usually taught for use in the prior art. As demonstrated below, it is applicants' contention that the prior art, and particularly the art relied upon by the Examiner to reject the present claims, actually teaches away from the presently claimed method by teaching the ordinary skilled artisan in this field the use of much higher doses of EPO than those presently claimed for the various uses of EPO as disclosed in the subject references.

Turning first to the Fatouros reference, notwithstanding the fact that the reference does not teach pulmonary or oral administration of EPO or the use of an additional ingredient that stimulates endothelial progenitor cells, the authors do teach on p. 987, left column, second full paragraph, to administer a dose of 500 IU EPO/kg of body weight in daily doses. These (daily) doses are significantly higher than the (weekly) doses recited in applicants' claims. Nor does the reference contain any teaching which would suggest lowering the dose taught for use therein to any dosage approximating that recited in applicants' claims.

Turning next to the '158 U.S. patent to Zaharia Czeizler ("Czeizler"), as noted above this reference relates not to the treatment of wounds, as does applicants' presently claimed method. Instead, it relates to the treatment of bleeding in patients. That is, as indicated in (for example) the Abstract of the subject patent, the method claimed by the patentee consists of the subcutaneous, intravenous or oral administration of recombinant human Erythropoietin for the purpose of preventing or stopping bleeding, e.g., in patients with congenital or acquired disorders of coagulation, platelets or vessels as well as patients on therapeutic or overdose of anticoagulants or antiplatelet drugs.

Furthermore, notwithstanding that the patent teaches the use of EPO for a purpose different from that recited in applicants' claims, it is further noted that the reference teaches to use significantly higher dosages of EPO than that which is claimed by applicants. In particular, as taught by the patentee in cols. 3-4 of the reference, a first or initial treatment with EPO is envisaged using dosages substantially higher than those chosen for use by the present applicants, such as 5,000 IU EPO/day (see Example 1), or three times per week (see Example 2) or 4,000 IU three times per week

(see Example 3). Under the assumption, therefore, that an average patient has a body weight approximating 75 kg, it is noted from the discussion above that the subject patent teaches to use a significantly higher dosage than that which is recited in applicants' claims. Furthermore, it is additionally important to note that, in addition to the initial EPO treatments referred to above, the reference also teaches (see the Examples) that the patients subsequently received additional treatments with EPO, thus further increasing the amount of EPO administered.

Still further, as also demonstrated by the Examples, the EPO dosages used significantly increased the haemoglobin values obtained with the blood of the patients (see, e.g., col. 4, line 44, col. 5, lines 24-25, col. 7, line 28, etc.). This is in clear contrast to applicants' presently claimed invention wherein the aim is to heal wounds and to do so without affecting the haemoglobin value, i.e., referred to as the hematocrit value. In this regard the applicants respectfully direct the Examiner's attention to p. 27 of their application (line 9, et seq.) which teaches that the doses provided according to the present invention are subpolycythemic doses, i.e., doses which do not lead to erythrocytosis (with hematocrit values >50%) which means that the amount of haemoglobin in the system is not significantly increased. Further in contrast to the present invention, moreover, the reference teaches at col. 5, line 56 to use even higher doses of EPO at more frequent transfusions to achieve the desired result which, as noted above, is not the result sought by the use of applicants' claimed method.

Applicants turn, next, to the Amgen reference, i.e., EP 0 613 683. This reference contains no teaching relating to the healing of wounds. Furthermore, as noted above, it teaches to use (for preparing a pharmaceutical composition suitable for pulmonary administration or inhalation) significantly higher doses of EPO than are contemplated for use by applicants in their claimed method. This is evident from, e.g,. the disclosure found at p. 5, lines 9-10 (500, 1500 and 4500 IU/kg of EPO) and p. 8 lines 33-35 (500 IU/kg). As is also evident from, e.g., Fig. 4 of the reference, at least one aim of the method described therein is to significantly increase the hematocrit value - another factor upon which the presently claimed method, which envisions no such increase, may be distinguished.

In summary, therefore, not only do several of the references cited to reject the present claims utilize EPO for purpose(s) different than that of the presently claimed method, but each of the references which contains a teaching to administer EPO (Note: the Krussel et al. reference is cited due to its teaching to use the compound VEGF to stimulate endothelial progenitor cells and induce

angiogenesis, which the Examiner has interpreted as falling within the scope of 'wound healing' - it is not, however, directed to the administration of EPO) actually teaches away from the practice of the presently claimed method by teaching to use significantly higher dosages of EPO than the 1 to 90 IU EPO/kg of body weight per week recited in applicants' claims. Thus, applicants contend that the references discussed above would neither teach nor suggest the presently claimed method to one having ordinary skill in this art, whether viewed individually or in combination.

Based on the reasons above, therefore, the Examiner is respectfully requested to reconsider and withdraw the rejection under 35 USC 103.

The Double Patenting Rejection

On p. 5 of the present Office Action, claims 46, 52, 53, 59, 65, 70 and 90 are provisionally rejected on the ground of non-statutory obviousness-type double patenting over claims 4, 15-31 and 35-44 of co-pending application Serial No. 10/586,896. This provisional rejection is respectfully traversed.

The present state of affairs appears to applicants to fall within the scope of the situation outlined in M.P.E.P. §804 I(B), i.e., dealing with provisional obviousness-type double patenting rejections between two (or more) co-pending applications. According to the M.P.E.P., however, when and if the provisional double patenting rejection is the only rejection remaining in one of the two co-pending applications, the Examiner should withdraw the rejection to permit the application to issue as a patent and convert "the provisional double patenting rejection in the other application(s) [i.e., Serial No. 10/586,896] into a double patenting rejection at the time the one application [i.e., the present application] issues as a patent." Applicants respectfully submit that they believe, based on the remarks provided in the portion of the response above dealing with the rejection under §103, that the subject 'obviousness' rejection has been overcome and, thus, the obviousness-type double-patenting rejection would be the only ground of rejection remaining in the present application. As such, the Examiner is respectfully requested to withdraw the rejection in the present case, so that it can proceed to issuance, and to thus deal with the issue in applicants' co-pending application Serial No. 10/586,896.

Information Disclosure Statement

Submitted herewith is a copy of art together with a form listing the same for the convenience of the Examiner.

Also submitted herewith is a copy of a Chinese Office Action (with an English translation) as well as a copy of the references cited therein.

I respectfully request that the information submitted be considered and enclose our payment of the required $180.00 fee, being submitted via EFS-WEB.

In the event the actual fee is greater than the payment submitted or is inadvertently not enclosed or if any additional fee due during the pendency of this application is not paid, the Patent and Trademark Office is authorized to charge the underpayment to Deposit Account No. 15-0700.

Summary

If the Examiner is not prepared to withdraw the rejections of applicants' claims as set forth in the pending Office Action concerning this case and, yet, believes that an interview would materially advance the progress of this application, he is respectfully invited to telephone applicants' representative at the number below so that an interview concerning this case may be scheduled.

Respectfully submitted,

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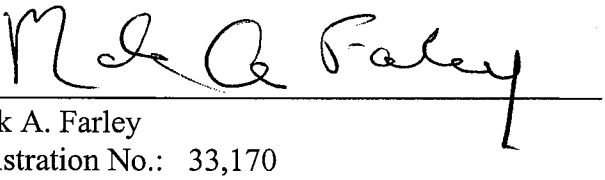

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